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10/039,644

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,644	12/19/2001	Erika Lynn Hadeed		9283

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/039,644	HADEED, ERIKA LYNN
Examiner	Art Unit	
Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 December 2001.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 12/19/2001.
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

**1.** An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. This application claims priority to a provisional application; however, a specific reference to the provisional application has not been made in the specification or the application data sheet.

### *Claim Rejections - 35 USC § 112*

**2.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**3.** Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it fails to positively define how the different parts of the device are related or connected. For example, it appears that the device of claim 1 comprises four different and separate parts, an absorbent material, a support means holding a membrane immunoassay, a casing and a cap. There is no positive recitation that the absorbent material and the support means holding the membrane is positioned inside the casing and that the cap

covers the first absorbent material and forming a tight fit with the casing. Furthermore, there is no recitation as to the function and location of the turning joint and the latch. Although it may be apparent that the turning joint is for turning, it is not clear what is being turned; nor is it clear that the housing may consists of two halves joined by the turning joint and closable by the latch. In other words, no relationship exists between the absorbent material and the casing, nor is there any relationship between the membrane immunoassay and the casing.

Furthermore, the recitation of an “optional” material is not considered a positive limitation of the claim and thus has not been considered.

Claims 5 and 6 are indefinite because the casing is not recited as being made up of two halves connected by a turn joint, therefore, it is unclear how the casing can be opened via the turn joint.

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 6,514,769 B2) in view of Chandler et al (US 5,877,028).

Lee discloses an assay device comprising a test strip having a sample loading zone (e.g. an absorbent pad or bibulous membrane) in fluid communication with test and control zones. The test and control zones have immobilized reagents for detection of analytes. See column 7, lines 21-39; and lines 51-59. The test strip is supported on a carrier membrane (e.g. support means), and the entire assembly is disposed in a housing (e.g. casing). See column 7, lines 3-12. Lee teaches that in a preferred embodiment, the housing comprises a base and a cover, and the base having slots separated by fluid constriction rails (e.g. flange) defining channels for insertion of the test strip, and most preferable, the housing may be opened to permit substitution of different analyte test strips to allow each device to be customized for detection of specific analytes. See column 2, lines 31-36; and column 9, lines 21-39. The cover is provided with transparent windows through which the test results may be observed, and the protruding ends of the sample loading zone is protected by a cap. See column 9, lines 39-46.

Lee differs from the instant invention in failing to teach the means for opening and closing the casing.

Chandler, however, discloses chromatographic assay device for use with immunoassays. The device of Chandler comprises two opposable components joined by a hinge. The first and second opposable components further comprise engagers (latch holder and latch release grip) such as locks that secure the first and second opposable components together or to hold them apart. See specifically column 20, lines 38-58 and figure 1A.

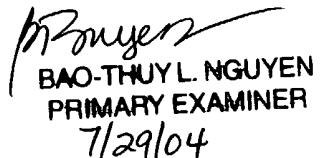
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the housing taught by Lee to include the hinge and engagers of Chandler in order to facilitate the opening and closing of the housing as taught by Lee. The use of hinges and engagers such as those taught by Chandler is well known in the art and a skilled artisan would have had a reasonable expectation of success in using them in the housing of Lee because Lee teaches that the housing may be opened to permit substitution of different analyte test strips to allow each device to be customized.

*Conclusion*

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
7/29/04